

Memorandum

Date: = **OCT 11 2006**

From: Consumer Safety Officer, Division of Dietary Supplement Programs , Office of
Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: **“Diosmin”**

Firm: Natural ASA

Date Received by FDA: July 6, 2006

90-Day Date: October 4, 2006

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and
Cosmetic Act, the attached 75-day premarket notification and related correspondence for the
aforementioned substance should be placed on public display in docket number 95S-0316 as
soon possible since it is past the 90-day date. Thank you for your assistance.

 Victoria Lutwak

1995S-0316

RPT 358



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

SEP 19 2006

Mr. Irving L. Wiesen, Esq.
Ullman, Shapiro and Ullman, LLP
420 Lexington Avenue, Suite 2400
New York, New York 10170

Dear Mr. Wiesen:

This is to inform you that the notification, dated June 30, 2006, that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) on behalf of your client, Exquim, S. A., was filed by the Food and Drug Administration (FDA) on July 6, 2006. Your notification concerned the substance that you called "Diosmin" that you intend to market as a new dietary ingredient under the trade name, "DiosveinTM".

According to your notification, the daily serving level of your ingredient will be 500 mg/day. Your notification states that the "[m]aximum recommended duration of use [will be]: 3 months. Not recommended for use by children or pregnant or nursing women."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21U.S.C. 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

In accordance with 21 CFR 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, your firm must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains the dietary ingredient that is the subject of this notification.

Please note that acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342. FDA is not precluded from taking action in the future against any dietary supplement containing your new dietary ingredient if it is found to be unsafe, adulterated or misbranded.

This letter supercedes FDA's letter dated September 19, 2006.

Your notification will be kept confidential for 90 days after the filing date of July 6, 2006. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter please contact Victoria Lutwak at (301) 436-1775.

Sincerely yours,

A handwritten signature in cursive script that reads "Linda S. Pellicore".

Linda S. Pellicore, Ph.D.
Supervisory Team Leader, Senior Toxicologist
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition

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Irving L. Wiesen *
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New York, New York

June 30, 2006

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

Re: New Dietary Ingredient Submission: DIOSMIN

Dear Sir/Madam,

Enclosed please find a New Dietary Ingredient (NDI) submission for Diosmin (brand name: Diosvein™) filed on behalf of:

Edifici L'Illa
Av. Diagonal, 549 5th floor
08029 Barcelona, SPAIN

This submission is made pursuant to 21 CFR 190.6.

AIMS
2006-5561

Please contact the undersigned for any further communications regarding the within submission.

Sincerely,

A handwritten signature in black ink, appearing to read 'Irving Wiesen', with a stylized, cursive script.

Irving Wiesen